

recall since the last report and the results of these steps.

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter for transmittal to the Center for Food Safety and Applied Nutrition (HFS-605), for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Center for Food Safety and Applied Nutrition (HFS-605), of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such a notification unless it has information, from FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or

(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004]

EFFECTIVE DATE NOTE: At 79 FR 8075, Feb. 10, 2014, § 107.250 was amended by revising the introductory text, effective July 10, 2014. For the convenience of the user, the revised text is set forth as follows:

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate FDA district office for transmittal to the Recall Coordinator, Division of Enforcement (HFS-605), Office of Compliance, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or by email to CFSAN.RECALL@fda.hhs.gov, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The Agency will

respond within 15 days of receipt by the Division of Enforcement of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the Agency that the recall has been terminated. The Agency will send such notification, unless the Agency has information from FDA's own audits or from other sources demonstrating that the recall has not been effective. The Agency may conclude that a recall has not been effective if:

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§ 107.260 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

(a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.

(b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.

(c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information demonstrate that the original notifications were not received, or were disregarded in a significant number of cases.

§ 107.270 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonable calculated to meet the obligations set forth in this Subpart E. The recall guidance in subpart C of part 7 of this chapter specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

[54 FR 4008, Jan. 27, 1989, as amended at 65 FR 56479, Sept. 19, 2000]

§ 107.280 Records retention.

Each manufacturer of an infant formula shall make and retain such